PCT/EP2003/010049

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 28642P WO/HBwr	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP2003/010049	International filing date (*day/month/year*) 10 September 2003 (10.09.2003)	Priority date (*day/month/year*) 10 September 2002 (10.09.2002)
International Patent Classification (IPC) or national classification and IPC A61L 29/16		
Applicant PROF. DR. JOSEF-PETER GUGGENBICHLER, DR. CHRISTOPH CICHOS GBR		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 3 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 05 April 2004 (05.04.2004)	Date of completion of this report 09 December 2004 (09.12.2004)
Name and mailing address of the IPEA/EP Facsimile No.	Authorized officer Telephone No.

Form PCT/IPEA/409 (cover sheet) (July 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/EP2003/010049

I. Basis of the report

1. With regard to the **elements** of the international application:*

☐ the international application as originally filed

☒ the description:

pages 1-19, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____

☒ the claims:

pages _____, as originally filed

pages _____, as amended (together with any statement under Article 19

pages _____, filed with the demand

pages 1-17, filed with the letter of 17 November 2004 (17.11.2004)

☒ the drawings:

pages 1/3-3/3, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____

☐ the sequence listing part of the description:

pages _____, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-17	YES
	Claims		NO
Inventive step (IS)	Claims	1-17	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-17	YES
	Claims		NO

2. Citations and explanations

The present application concerns plastics items which contain in addition to an anti-microbial colloidal metal a soluble or slightly soluble anti-microbial metal salt, and a method for the production thereof.

1. Documents

1.1. Reference is made to the following documents:

D1: WO 01 24839 A (ACRYMED; GIBBINS BRUCE L (US); HOPMAN LANCE D (US)) 12 April 2001 (2001-04-12)

D2: WO 01 43788 A (BARD INC C R) 21 June 2001 (2001-06-21)

D3: DE 199 36 059 A (GUGGENBICHLER J PETER; HIRSCH ANDREAS (DE)) 1 February 2001 (2001-02-01)

1.2. Unless indicated otherwise, the passages of text referred to are those cited in the search report.

2. Novelty

2.1. Document D1 describes a polymer matrix containing silver chloride colloids (see claims 1 and 7 to 9).

Copper chloride may also be added for stability.

2.2. Document D2 provides medical items that allow a rapid initial release of anti-microbial metal salts followed by an extended activity phase (page 10, lines 9 to 17). Said items contain colloids consisting of metal salts with differing degrees of water solubility (zinc iodide, silver nitrate, zinc nitrate, silver lactate, silver acetate, silver chloride, etc.) which allow the desired release profile to be set (example 14).

A prefabricated plastics catheter can be treated with the corresponding colloid-metal salt composition (example 15).

2.3. D3 concerns catheters that contain colloidal silver and therefore have a high level of anti-microbial activity and improved long-term performance.

2.4. None of the documents discloses a combination of anti-microbial colloidal metals with a (soluble or slightly soluble) anti-microbial metal salt. Consequently, the product as per claims 16 and 17 and also the method for producing the product (claims 1 to 15) are novel (PCT Article 33(2)).

3. Inventive step

3.1. Document D3, which is regarded as the closest prior art, discloses prefabricated polyurethane catheters that are treated with a primary metal colloid and are distinguished by the low level of toxicity and at the same time high level of long-lasting anti-microbial activity.

3.2. The present application differs from D3 by the further addition of a soluble or slightly soluble anti-microbial metal salt.

3.3. The addition of a metal salt produces not only an improved anti-microbial long-term effect, but also a considerably improved immediate effect.

3.4. The present invention can therefore be considered to address the problem of "producing plastics products that have improved anti-microbial activity for the entire period of use".

3.5. Document D2 looks in detail at the kinetics of various silver salts. By combining various silver salts it is possible to produce catheters that have a rapid initial release as well as a long-term effect. By selecting suitable silver salts, an individual release profile for the silver ions can be set.

3.6. D2 does not, however, contain anything that would prompt a person skilled in the art to combine the silver salts from D2 with colloidal silver in order to produce the desired release characteristic. On the contrary, D2 highlights the disadvantages of using metallic silver and asserts that not enough silver is released.

3.7. The solution proposed in claim 1 of the present application can therefore be considered inventive (PCT Article 33(3)). The same applies to the item produced according to claims 1 to 15, which is distinguished by a rapid anti-microbial immediate effect within the space of a few hours and also by a

long-term effect lasting weeks and months.

3.8. Consequently, claims 1 to 17 meet the PCT requirements with respect to novelty and inventive step.

4. Industrial applicability

4.1. Claims 1 to 17 of the present application meet the requirements for industrial applicability (PCT Article 33(4)).